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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,016	05/05/2004	Janet F. Morrison	03141.000002.	9645
5514 7590 01/19/2007 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EXAMINER VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,016	MORRISON ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 26, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 6-10, 12-16 and 72-76, drawn to a method comprising, *inter alia*, an on-line extraction, classified in class 600/380, for example.
- II. Claims 2-11, 14-16, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a charged group and an agent, classified in class 95/57, for example.
- III. Claims 17-26, 38-60, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a reactive hydrogen and an agent, classified in class 424/1.81, for example.
- IV. Claims 27-29, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a reactive carboxyl group and an agent, classified in class 436/129, for example.
- V. Claims 30-34, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a reactive hydrogen, a reactive carboxyl group, and an agent, classified in class 424/1.53, for example.
- VI. Claims 35-37, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a reactive hydrogen, a reactive carboxyl group, and two or more agents, classified in class 435/DIG. 2, for example.
- VII. Claims 61, 72, 73 and 76, drawn to a method comprising, *inter alia*, metabolic incorporation, classified in class 424/9.2, for example.
- VIII. Claims 62, 63, 72, 73 and 76, drawn to a method comprising, *inter alia*, enzyme degradation, classified in class 435/262, for example.
- IX. Claims 67-69, 72, 73 and 76, drawn to a method comprising, *inter alia*, extracting carbohydrates, classified in class 127/1, for example.
- X. Claims 70, 72, 73 and 76, drawn to a method comprising, *inter alia*, a reaction between a sugar ring substituent group and an agent, classified in class 436/131, for example.
- XI. Claims 71-73 and 76, drawn to a method comprising, *inter alia*, extracting with detergents, classified in class 210/645, for example.
- XII. Claims 64-66, drawn to a product packet, classified in class 53/111 RC, for example.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I to XI are related processes. Related processes are distinct from each other if the processes, *as claimed*, are not: (1) capable of use together or have a materially different design, mode of operation, function, or effect; (2) overlapping in scope, i.e., are mutually exclusive; and (3) obvious variants. See MPEP § 806.05(j).

Here, Inventions I to XI have different modes of operation because Invention I requires an on-line extraction, while Invention II requires a reaction between a charged group and an agent, while Invention III requires a reaction between a reactive hydrogen and an agent, while Invention IV requires a reaction between a reactive carboxyl group and an agent, while Invention V requires a reaction between a reactive hydrogen, a reactive carboxyl group, and an agent, while Invention VI requires a reaction between a reactive hydrogen, a reactive carboxyl group, and two or more agents, while Invention VII requires metabolic incorporation, while Invention VIII requires enzyme degradation, while Invention IX requires extracting carbohydrates, while Invention X requires a reaction between a sugar ring substituent group and an agent, while Invention XI requires extracting with detergents.

The scopes of Inventions I to XI do not appear to overlap because Inventions I to XI, each requiring different modes of operation and producing different effects, do not appear to infringe each other. In addition, there is no indication on the record of a specific example of a single process that infringes two or more of Inventions I to XI.

Inventions I to XI are not obvious variants because Inventions I to XI require different steps involving different compounds having different kinetic activities measured with different detection means under different optimized conditions. Furthermore, there is no indication on the record that the Inventions would have been obvious variants over each other within the meaning of 35 U.S.C. 103(a).

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Inventions (I to XI) and XII are related as processes and apparatus for its practice.¹ The inventions are distinct if it can be shown that either: (1) the processes as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus of Invention XII can be used to pull shots of espresso.

Examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for on-line extraction of Invention I requires a search of prior art related to lungs, while a search for the reaction between a charged group and an agent of Invention II requires a search of prior art related to capacitance, while a search for the reaction between a reactive hydrogen and an agent of Invention III requires a search of prior art related to kinetic isotope effects, while a search for the reaction between a reactive carboxyl group and an agent of Invention IV requires a search of prior art related to carboxylic acid chemistry, while a search for the reaction between a reactive hydrogen, a reactive carboxyl group, and an agent of Invention V requires a search of prior art related to bifunctional linkers, while a search for the reaction between a reactive hydrogen, a reactive carboxyl group, and two or more agents of Invention VI requires a search of prior art related to multi-order reaction equilibria, while a search for metabolic incorporation of Invention VII requires a search of prior art related to livers and kidneys, while a search for enzyme degradation of Invention VIII requires a search of prior art related to proteases, while a search for carbohydrate extraction of Invention IX requires a search of prior art related to glycogen catabolism, while a search for the reaction between a sugar ring substituent group and an agent of Invention X requires a search of prior art related to boronate

¹ Examiner requires restriction between product and process claims. Where Applicant elects to prosecute claims directed to a product, and the product claims are subsequently found allowable, Examiner will consider withdrawing the instant restriction requirement and rejoining non-elected, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims (*i.e.*, all the process claims must include all the limitations of the allowable product claims). Examiner will not rejoin non-elected, withdrawn process claims that are not commensurate in scope with the allowable product claims. See MPEP § 821.04(b). Thus, where Applicant elects to prosecute claims directed to a product, Examiner advises Applicant to continually amend the non-elected, withdrawn process claims during prosecution to require all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Upon rejoinder, Examiner will fully examine the rejoined process claims in accordance with 37 CFR 1.104 for compliance with all criteria for patentability, including the requirements of 35 U.S.C. 101, 102,

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chromatography, while a search for detergent extraction of Invention XI requires a search of prior art related to dry cleaning, while a search for the apparatus of Invention XII requires a search of prior art related to espresso machines.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

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This application contains claims directed to the following patentably distinct groups of species:

1. Select ONE fluid from:

- a. Carbon dioxide; (claims 3, 6, 7, 9, 15)
- b. Nitrous oxide; (claim 3)
- c. Pentane; OR (claim 3)
- d. Butane. (claim 3)

2. Select ONE analyte substituent from:

- a. Hydroxyl; (claims 4, 18)
- b. Carboxyl; (claim 4)
- c. Amide; (claims 4, 18)
- d. Amine; (claims 4, 18)
- e. Thiol; OR (claims 4, 18)
- f. Aryl. (claim 18)

3. Select ONE derivatizing agent from:

- a. Alkylating, methylating; (claims 5, 19)
- b. Acylating; (claims 5, 19)
 - i. anhydride; (claim 20)
 - ii. acyl halide; (claim 20)
 - 1. perfluoro acid anhydride; (claims 22, 37)
 - a. trifluoroacetic acid anhydride; (claims 23)
 - b. pentafluoropropionic acid anhydride; (claim 23)
 - c. heptafluorobutyric acid anhydride; (claim 23)
 - 2. perfluoroimidazole; (claim 22)
 - a. trifluoroacetylimidazole; (claim 24)
 - b. pentafluoropropionylimidazole; (claim 24)
 - c. heptafluorobutyrylimidazole; (claim 24)
 - 3. N-methyl-bis(trifluoroacetamide); (claims 22, 25)
 - iii. activated acyl amide; (claim 20)
 - 1. acylimidazole; (claim 21)
 - 2. bis(acylamide); (claim 21)
- c. Silylating; (claims 5, 19)
- d. Esterifying. (claims 19, 28)
 - i. Pentafluoropropanol; OR (claim 29)
 - ii. Anhydride. (claim 29)

4. Select ONE modifier from:

- a. Methanol; (claims 8, 39, 65)
- b. Dichloromethane; (claims 8, 39, 65)
- c. Ethanol; (claims 8, 39, 65)
- d. Ethyl acetate; (claims 8, 39, 65)
- e. Isopropanol; (claim 8)
- f. Hexane; (claim 8)
- g. Dichloroethane; (claims 39, 65)
- h. Acetone; OR (claims 39, 65)
- i. Methyl acetate. (claim 39)

5. Select ONE additive from:

- a. Methylamine; (claim 10)
- b. Dimethylamine; (claim 10)
- c. Trimethylamine; (claim 10)
- d. Butylamine; (claims 10, 41)
- e. Water; (claim 10)

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- f. Diethylamine; OR (claim 41)
 - g. Triethylamine. (claim 41)
6. Select ONE analyte from:
- a. Drug; (claims 12, 76)
 - i. cocaine; (claims 13, 34)
 - 1. benzoylecgonine; (claim 34)
 - 2. cocaethylene; (claim 34)
 - ii. heroin; (claim 13)
 - iii. 6-monoacetylmorphine (*i.e.*, 6-MAM); (claims 13, 34)
 - iv. opium; (claim 13)
 - 1. morphine; (claims 13, 34)
 - 2. codeine; (claims 13, 34)
 - v. methamphetamine, amphetamine; (claims 13, 26, 34)
 - 1. methylenedioxyamphetamine (*i.e.*, MDA),
methylenedioxymethamphetamine (*i.e.*,
MDMA), methylenedioxyethylamphetamine
(*i.e.*, MDEA); (claim 13, 26, 34)
 - vi. PCP; (claims 13, 34)
 - vii. Δ -9-THC; (claims 13, 34)
 - 1. Δ -9-THC acid; (claims 13, 34)
 - 2. dihydroxyl THC; (claim 34)
 - viii. phencyclidine; (claim 13)
 - b. Pesticide; (claim 12)
 - c. Herbicide; (claim 12)
 - d. Environmental toxin; (claim 12)
 - e. Carcinogen; (claim 12)
 - f. Nicotine; (claim 34)
 - i. Cotinine; (claim 34)
 - g. Polar; (claims 73, 75)
 - h. Non-polar; OR (claim 73)
 - i. Polar and Non-polar. (claim 73)
7. Select ONE assay format from:
- a. Immunoassay; OR (claim 16)
 - b. GC/MS. (claim 16)
8. Select ONE zwitterionic compound from:
- a. Zwitterionic detergent; (claim 46)
 - i. CHAPSO; (claim 47)
 - ii. CHAPS; (claim 47)
 - iii. NDAPS; (claim 47)
 - iv. Phosphatidylcholine dipalmitoyl; (claim 47)
 - b. Amino acid; (claim 46)
 - c. Glycolipid; OR (claim 46)
 - d. Amino sugar. (claim 46)
9. Select ONE antifoaming agent from:
- a. Antifoam 204; (claims 50, 58)
 - b. Antifoam 289; (claims 51, 59)
 - c. Antifoam A; (claims 52, 60)
 - d. Antifoam B; (claims 52, 60)
10. Select ONE anionic detergent from:
- a. Alginic acid; (claim 54)
 - b. Caprylic acid; (claim 54)
 - c. Cholic acid; (claim 54)

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- d. Decane sulfonic acid; (claim 54)
 - e. Dehydrocholic acid; (claim 54)
 - f. Deoxycholic acid; (claim 54)
 - g. Dioctyl sulfosuccinate; (claim 54)
 - h. Dodecanesulfonic acid; (claim 54)
 - i. Glycocholic acid; (claim 54)
 - j. Glycodeoxycholic acid; (claim 54)
 - k. Heptane sulfonic acid; (claim 54)
 - l. Hexane sulfonic acid; (claim 54)
 - m. Lauroylsarcosine; (claim 54)
 - n. Lauryl sulfate; (claim 54)
 - o. Nonanesulfonic acid; (claim 54)
 - p. Octanesulfonic acid; (claim 54)
 - q. Pentanesulfonic acid; (claim 54)
 - r. Taurocholic acid; (claim 54)
 - s. Taurodeoxycholic acid; (claim 54)
 - t. TEEPOL® HB7; (claim 54)
 - u. TERGITOL®; OR (claim 54)
 - v. TRITON®. (claim 54)
11. Select ONE cationic detergent from:
- a. Alkyltrimethylammonium bromide; (claim 56)
 - b. Benzalkonium chloride; (claim 56)
 - c. Benzyldimethyldodecyl ammonium bromide; (claim 56)
 - d. Benzyldimethylhexadecyl ammonium chloride; (claim 56)
 - e. Benzyldimethyltetradecyl ammonium chloride; (claim 56)
 - f. Cetyldimethylethyl ammonium bromide; (claim 56)
 - g. Cetylpyridinium bromide; (claim 56)
 - h. Cetylpyridinium chloride; (claim 56)
 - i. Decamethonium bromide; (claim 56)
 - j. Dimethyldioctadecyl ammonium bromide; (claim 56)
 - k. Methylbenzethonium chloride; (claim 56)
 - l. Methyl mixed trialkyl ammonium chloride; (claim 56)
 - m. Methyl trioctylammonium chloride; OR (claim 56)
 - n. N,N',N'-polyoxyethylene(10)-N-tallow-1,3-diamino propane. (claim 56)
12. Select ONE enzyme from:
- a. Hexosaminidase; (claim 63)
 - b. Endoglycosidase; (claim 63)
 - c. Sialidase; (claim 63)
 - d. Galactoaminidase; (claim 63)
 - e. Glucosaminidase; (claim 63)
 - f. Glucosidase; (claim 63)
 - g. Galactosidase; (claim 63)
 - h. Phytase; OR (claim 63)
 - i. Chitinase. (claim 63)
13. Select ONE carbohydrate from:
- a. Glycoprotein; (claim 68)
 - b. Glycolipid; (claim 68)
 - i. Neutral glycolipid; (claim 69)
 - ii. Ganglioside; OR (claim 69)
 - iii. Sulfatide. (claim 69)
14. Select ONE sample from:
- a. Hair; (claim 72)
 - b. Feathers; (claim 72)
 - c. Nails; (claim 72)
 - d. Hoofs; (claim 72)

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- e. Skin; OR (claim 72)
- f. Muscle. (claim 72)

Applicants are required under 35 U.S.C. 121 to elect ONE disclosed specie member from each of groups 1 through 14, *supra*, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 2, 17, 27, 30, 35, 61, 62, 64, 67, 70 and 71 are generic.

With respect to species groups 1 through 13, the species members are independent or distinct by virtue of their different chemical structures having different kinetic activities measured with different detection means under different optimized conditions. With respect to species group 14, the species members are independent or distinct because each species member requires different sample processing and analyte extraction protocols.

Applicants are advised that a complete reply to this requirement must include: (i) an election of an invention and species even if the requirement is traversed² (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention and species. Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the

² Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect with traverse. Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should clearly admit on the record, or submit or identify evidence on the record that the inventions or species are obvious variants. If Examiner finds one Inventions unpatentable over the prior art, Examiner may use the evidence or admission of record to reject other inventions under 35 U.S.C.103(a).


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examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

djv


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